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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,423	03/01/2004	Pascal J. Goldschmidt-Clermont	1579-890	4961

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/788,423	GOLDSCHMIDT-CLERMONT ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *3,5,7,9 and 14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-13, and species election drawn to endothelial progenitor cells is acknowledged. The traversal is on the ground(s) that groups II & I are similarly classed and subclassed and a search of these claims can be made without serious burden. This is not found persuasive because it is maintained that each of the Inventions requires a separate search status and consideration. The inventions are mutually exclusive and independent methods for treating a particular disease or delivering agents. For example, group II does not require a therapeutic effect for atherosclerosis, and group I does not require delivering an agent. As such, the Invention of group II requires different reagents, steps, protocols, and technical considerations than the Invention of group I. The searches for groups II and I may have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02" (emphasis added).

Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-26 are pending, however, claims 3, 5, 7, 9 14-26 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

It is noted, upon search and consideration, another species, the hematopoietic or stromal fraction of bone marrow has been rejoined with the EPC, since there is no severe search burden.

Claims 1, 2, 4, 6, 8, 10-13 are under current examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 8, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by *Linton et al* (Science 1995;267:1034-7), and as evidenced by *Reyes et al* (J Clin Med 2002;109:337-46).

Linton et al teach intravenous administering (BMT, mid-column, page 1037) normal (heterologous) bone marrow cells to ApoE-deficient mice (an art-recognized animal model for atherosclerotic disease) significantly reduced serum cholesterol levels of ApoE-/- mice. Two months after BMT, BMT recipient mice were challenged with high-fat diet for three months. Upon conduction of quantitative analysis of aortic atherosclerosis, *Linton et al* reported dramatic reduction of atherosclerotic lesion in normal BMT recipient mice compared to apoE-/- BMT recipient mice (e.g. page 1036). *Linton et al* concluded that transplantation of normal bone marrow into ApoE-/- mice results in correction of hypercholeserolemia and prevention of aortic and coronary atherosclerosis. Although not relied upon, it was well known in the art bone marrow cells contain endothelial progenitor cells that mature into vascular endothelial cells as taught by *Reyes et al*. Accordingly, *Linton et al* anticipate instant claims.

Claims 1, 2, 4, 6, 8, 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ishimori et al* (J Leuk Biol 2001;69:732-40).

Ishimori et al teach intravenously administering a mixture of normal heterolgous bone marrow cells (SJL/J) to ApoE-deficient mice with hypercholesterolemia and preexisting atherosclerotic lesions. *Ishimori et al* reported significant reduction of the cholesterol level and significant lesion

regression of the atherosclerosis (e.g. the abstract, fig.4, and table 1). *Ishimori et al* concluded the resistance of SJL to atherosclerosis resides in the bone marrow-derived cells (e.g. page 738). Accordingly, *Ishimori et al* anticipate instant claims.

Claims 1, 2, 4, 6, 8, 10, 11 are rejected under 35 U.S.C. 102(a) as being anticipated by *Sakai et al* (Atherosclerosis 2002;161:27-34).

Sakai et al teach intravenously administering a mixture of normal heterolgous bone marrow cells with Apo-E deficient bone marrow cells (chimerism) to ApoE-deficient mice as a stem cell gene therapy strategy, and tested minimal requirement for the proportion of normal bone marrow. *Sakai et al* teach that 10% chimerism could significantly reduce the severity of the atherosclerosis (e.g. the abstract, fig.4, and § 3.3). Since bone marrow cells contain endothelial progenitor cells that mature into vascular endothelial cells. Accordingly, *Sakai et al* anticipate instant claims.

Claims 1, 2, 4, 6, 8, 10, 11 are rejected under 35 U.S.C. 102(a) as being anticipated by *Rauscher et al* (AHA 2002 November, IDS).

Rauscher et al teach intravenous administering heterologous unfractionated bone marrow cells to ApoE-deficient mice and significantly reduce the atherosclerotic lesions throughout the arterial tree. Accordingly, *Rauscher et al* anticipate instant claims.

Claims 1, 2, 4, 6, 8, 10-13 are rejected under 35 U.S.C. 102 (a) as being anticipated by *Werner et al* (Arterioscler Thromb Vasc Biol 2002;22:1567-72).

Werner et al teach vascular injury induced atherosclerosis and treatment strategy using a carotid injury model. Gene marked bone marrow cells were administered six months prior to injury (prophylactic), and 10 days before the vascular injury (column 1, page 1568), the mice received daily doses of rosuvastatin (a proteinceous or non-proteinceous anti-atherosclerotic agent). *Werner et al* reported bone marrow cells are found predominantly at the endothelial monolayer (fig. 2c), and treatment with rosuvastatin enhanced the circulating pool of endothelial progenitor cells and accelerated bone marrow-dependent reendohelialization of injured vascular wall in atherosclerosis (e.g. pages 1569-70, and fig. 4). Accordingly, *Werner et al* anticipate instant claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
October 26, 2006